UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,272	10/17/2001	Michael Rud Lassen	LASSEN=2A	4444

1444 7590 03/28/2002

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/978,272	Lassen et al
Examiner	**Art Unit**
Mosher	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *11/6/2001, 1/16/2002, 10/17/2001, 3/11/2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6 and 11-18* is/are rejected.

7) ☒ Claim(s) *7-10 and 19-44* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Objections

Claims 7-10, 19-44 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Therefore only claims 1-6 and 11-18 have been examined on the merits:

Claim Rejections - 35 USC § 112

Claims 1-6 and 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The are confusing, as it is not clear what is meant by "a RS virus related biological cell." The term "cell" is commonly understood in the art of biology, but claim 4 recites that the "cell" is a virus particle, which is contrary to the ordinary meaning of the term. The only working example in the specification involves detection of a glycoprotein, which is not a "cell" in any common meaning of the term. Although an applicant is permitted to be his own lexicographer, the specification does not contain a clear definition of the intended meaning of "cell." Therefore, the metes and bounds of "biological cell" are not clear. Furthermore, the intended scope of "RS virus related" is not clear. Does this mean an RSV-infected cell, or does it mean detecting viruses that are in some sense related to RSV, and if the latter is intended, what range of viruses are

considered related (e.g., any pneumovirus, any paramyxovirus, any positive-stranded RNA virus, any RNA virus, any virus)?

Also, the preamble in claim 1 recites "in an amount of less than about 2000 per microliter..."; what is there less than 2000 of in each microliter? Is there a limit upon the total volume assayed, as well as an upper limit on the concentration of analyte?

Also, in claim 1, the claim requires a "targeting species capable of directly detecting...RS virus..." in parts ii and iv, where the part iv species is linked to a polymeric carrier, and the part ii species is bound to the solid support. Is the intent to couple the targeting species to the solid support via the polymeric carrier, or is the intent a sandwich assay format, where the unbound detector material links the targeting species to a label via a polymer (like the working example)?

Further, claim 1, parts ii and iv, lacks antecedent basis for "said predetermined RS...". If you have previously determined RS virus, why bother to detect it again? Also, it is not clear if the "targeting species capable of directly detecting" in parts ii & iv is related to, or independent from, the "labeling species" of part v. That is, since a targeting species can't be detected without some kind of label, a label seems implicitly required in parts ii & iv. Does the claim require two separate labels? What does the second one do? Would the invention be better described if it stated that the targeting material was capable of binding to the RS virus rather than capable of detecting the RS virus? It would seem logical that the detection is actually accomplished by observing the label of part iv.

In claim 2, the claim requires the conjugate to contain three functional groups that are reactive with each other. The claim, as written, requires an unstable product - how do you maintain the mutually reactive functional groups on the carrier, connecting moiety, and targeting/labeling species, after they are all conjugated together? Is the intent actually to require a conjugation product made by the process of linking the moieties together via reaction of functional groups?

In the interest of compact prosecution, the examiner assumes that the claims are intended to mean a sandwich assay kit, where the reporter comprises a label and a targeting species both attached to a polymeric carrier. However, this treatment does not relieve applicant of the burden of response to the above grounds of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,663,277), optionally further in view of either Burton et al (US 5,762,905) or Langedijk (US 6,077,511). Wang teaches antibodies conjugated to labeled polymeric microspheres, antibodies conjugated to a solid support (e.g. a dipstick), and their use in an assay to detect viruses such as cytomegalovirus (CMV). Wang provides a working example using a fluorescent label to detect "as few as several thousand CMV virions in 0.5 ml serum" (see Example 5). Wang also teaches that enzymatic amplification can be designed into the microspheres, although this is not a preferred embodiment, see column 5, lines 50-58. Wang teaches that the polymeric microsphere amplifies the sensitivity of the assay, see for example the passage spanning columns 5 and 6. Wang also explicitly suggests detection of respiratory syncytial virus (RSV) by the technique, see column 8, lines 33-34. Therefore it would have been obvious to carry out the explicit suggestion made in Wang. Furthermore, both Burton and Langedijk teach diagnostic tests for RSV using antibodies. It would have been within the ordinary skill of the art to substitute anti-RSV antibodies such as those taught by Burton or Langedijk for anti-CMV antibodies, with reasonable expectation of success. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of either Burton et al or Langedijk as applied to claims 1-6 and 11-15 above, and further in

view of Molday (US 4,452,773). These claims differ from the above in requiring a dextran polymer as carrier. Molday teaches a magnetic iron-dextran polymer microsphere which can be covalently bonded to antibodies. Since Wang teaches a magnetic label as a preferred embodiment (see column 5, lines 50-54 and Examples 3-4), it would have been obvious to substitute a magnetic microsphere such as that of Molday for the other microspheres used in Wang. The invention as a whole The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 1, 2, 4-6, 14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al or Burton et al or Langedijk et al, further in view of Lihme et al (US 5,543,332). Each of the primary references suggests an immunoassay to detect RSV. Lihme teaches that it is well known in the immunoassay art to enhance the sensitivity of immunochemical assay procedures by attaching an antibody and a plurality of enzyme molecules, fluorescent parker molecules, or the like to a polymeric carrier, see column 5, lines 18-50. Lihme et al also teaches that water-soluble polymers are preferable, and teaches a wide variety of suitable known water-soluble polymers, include hydroxyethyl and hydroxypropyl cellulose, see for example column 6, lines 1-16 or columns 11-12. It would have been within the ordinary skill of the art to combine art-known elements of the immunoassay art, such as a water-soluble polymeric carrier like hydroxyethyl cellulose or hydroxypropyl cellulose, with antibodies for RSV, for the purpose of improving the sensitivity of detection of RSV. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Singh et al (US 6,083,708) is cited as of interest as teaching use of water-soluble dendrimer/protein conjugates in immunoassays.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 25, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600